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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/837,562	04/19/2001	Edward Larry McCleary	12439.101B	7515

24283 7590 12/28/2004

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EXAMINER	
MCINTOSH III, TRAVISS C	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 12/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/837,562	MCCLEARY, EDWARD LARRY	
	Examiner	Art Unit	
	Traviss C McIntosh	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *26 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-64* is/are pending in the application.

4a) Of the above claim(s) *2-52 and 59-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 and 53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 24 and 59-64 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 26, 2004. Applicants argued that the restriction requirement was not set forth properly. The examiner agreed as groups II and III were not set forth correctly. As such, the examiner has included for applicant's convenience a revised restriction requirement to make the record clear. Additionally, the examiner contacted Mr. Carl Forest on December 21, 2004 to address the restriction requirement which was previously set forth incorrectly, and Mr. Forest elected group I drawn to the composition claims.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 53-58, and 65 (which is seen to be the same as claim 1), drawn to compositions comprising 6 various agents, classified in class 514, various subclasses depending on the items used in the composition.

II. Claim 66, drawn to a composition comprising 13 various agents, classified in class 514, various subclasses depending on the items used in the composition.

III. Claims 24, 59-64, and 67 (which is seen to be the same as claim 24), drawn to methods of treating neurological disorders using a composition which comprises 6

various agents, classified in class 514, various subclasses depending on the items used in the composition.

IV. Claim 68, drawn to methods of treating neurological disorders using a composition comprising 13 various agents, classified in class 514, various subclasses, depending on the items used in the composition.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct for the following reasons. The invention of Group I requires that the composition comprises 6 active agents. The invention of Group II requires that the composition comprises 13 active agents. A search for the composition of Group I would not necessarily disclose the invention of Group II. Moreover, a reference rendering Group I obvious would not necessarily render obvious Group II.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with the composition of Group I or the composition of Group II.

Inventions I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP

§ 806.05(h)). In the instant case the process as claimed can be practiced with the composition of Group I or the composition of Group II.

Inventions II and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with the composition of Group I or the composition of Group II.

Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process as claimed can be practiced with the composition of Group I or the composition of Group II.

Because these inventions are distinct for the reasons given above and the search required for Group II is not required for Group I, restriction for examination purposes as indicated is proper.

Moreover, because the compositions as claimed could be used in patentably different methods, and because the compositions comprise known compounds, restriction between compositions and methods is deemed proper.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 53-58 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way to convey reasonably to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a written description rejection.* Claims 1 and 53-58 do not contain complete generic formulas for the compositions sought protection for.

The MPEP states in §2163 II 3 ii) "The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406."

In the instant application, applicants are claiming compositions which optionally comprise various moieties which are defined using functional language. Moieties which are defined by the functional phrases include "at least one agent which promotes synthesis of ATP and/or creatine phosphate in the body", "at least one antioxidant for scavenging free radicals in at

least one pathway in the body", "at least one agent for treating or maintaining membrane function and structure in the body", "at least one agent for treating or maintaining normal neurotransmitter function in the body", "at least one agent for down-regulating cortisol action", "at least one agent for suppressing activation of apoptotic pathways in the body", and claim 55 provides that C is a "methyl donor". Each of the above functional phrases represents an independent genus of compounds, which were not described by an actual reduction to practice, reduction to drawings, or by a disclosure of relevant, identifying characteristics, i.e., by functional characteristics coupled with a known or disclosed correlation between function and structure, sufficiently to show the applicant was in possession of the claimed genus.

Applicants are reminded of what the U.S. Court of Appeals Federal Circuit wrote in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398, "In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is." See *Fiers*, 984 F.2d at 1169-71, 25 USPQ2d at 1605-06 (discussing Amgen). "It is only a definition of a useful result rather than a definition of what achieves that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention." See *In re Wilder*, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the

specification does "little more than outline goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate").

What are the structures of these molecules to be used in the compositions and where in the specification do Applicants teach how to make these potentially limitless structural variations of such molecules to be utilized in the claimed compositions? Case law is clear that such broad claims lack sufficient supporting description. Starting with a hormone case, which claimed a partially characterized peptide that was claimed in terms of its chemical properties, *In re Fisher*, 166 USPQ 18, the U.S. Court of Customs and Patent Appeals, wrote:

> It is apparent that such an inventor should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are still within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art. In cases involving predictable factors, such as mechanical or electrical elements, a single embodiment provides broad enablement in the sense that, once imagined, other embodiments can be made without difficulty and their performance characteristics predicted by resort to known scientific laws. In cases involving unpredictable factors, such as most chemical reactions and physiological activity, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved. In the present case we must conclude, on the record before us, that appellant has not enabled the preparation of ACTHs having potencies much greater than 2.3, and the claim recitations of potency of "at least 1" render the claims insufficiently supported under the first paragraph of 35 U.S.C. 112.

This concept was expanded by the U.S. Court of Appeals Federal Circuit in *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 USPQ2d 1016 in a case concerning EPO genes. Since genes

were held to be chemicals, the principle regarding enablement applies as well to all small molecules. The court held that:

> A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. See *Oka,* 849 F.2d at 583, 7 USPQ2d at 1171. Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.

These two cases were quoted with approval in *Genentech Inc v. The Wellcome Foundation Ltd.*, 31 USPQ2d 1161 by the U.S. Court of Appeals Federal Circuit, which added further in a concurring opinion "Such a claim, defining a substance only by its function, encompassing all substances that accomplish that result, is akin to a single means claim, which might fail to satisfy the definiteness requirement of 35 U.S.C Section 112. See *Fiers v. Sugano*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993)."

In *Fiers v. Sugano*, 25 USPQ2d 1601, U.S. Court of Appeals Federal Circuit repeated its views concerning the propriety of defining a chemical by its function and emphasized that for all chemicals including DNA "Claiming all DNA's that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived." They further required the inventor to have a "mental picture of the structure of the chemical, or is able to define it by its method of preparation, its

physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property."

Both *Fiers v. Sugano*, 25 USPQ2d 1601 and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.* 18 USPQ2d 1016 were quoted with approval by the U.S. Court of Appeals Federal Circuit in *Burroughs Wellcome Co. v. Barr Laboratories Inc.,* 32 USPQ2d 1915 who added, "An idea is definite and permanent when the inventor has a specific, settled idea, a particular solution to the problem at hand, not just a general goal or research plan he hopes to pursue. The conception analysis necessarily turns on the inventor's ability to describe his invention with particularity. Until he can do so, he cannot prove possession of the complete mental picture of the invention. These rules ensure that patent rights attach only when an idea is so far developed that the inventor can point to a definite, particular invention."

As set forth supra, applicants claim compositions which comprise various functionally defined moieties. Compounds with divergent structure are known to act similarly, and compounds with similar structure are known to act divergently. Applicants have failed to disclose the structures of the moieties intended, and have failed to disclose the correlation between function set forth and structure of the moieties intended. Applicants have not shown they were in possession of the compositions which comprise the various broad genuses of moieties which are set forth by their functional language.

Therefore the full breadth of the claims fail to meet the written description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision.

Applicants are encouraged to claim their compositions which indicates structurally, formulaically, or nomenclatorially the compounds which are to be included therein.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 53, and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Henningfield et al. (US Patent 5,221,668).

Claim 1 of the instant application is drawn to a composition comprising various agents which are defined by their function, as set forth supra.

Henningfield et al. disclose a composition which comprises: vitamin B12 (falls into categories A and C of claim 1), vitamin C (falls into category B of claim 1), choline (falls into category D of claim 1), vitamin B-6 (or pyridoxine - falls into category E of claim 1), and magnesium (falls into category F of claim 1) (see table 2).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 571-272-0657. The examiner can normally be reached on M-F 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Traviss C. McIntosh III
July 23, 2004

James O. Wilson
Supervisory Patent Examiner
Art Unit 1623